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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,452	01/14/2002	Oscar Jimenez	01078	4030
24628	7590	03/07/2005	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			RAYFORD, SANDRA M	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/046,452	Applicant(s) JIMENEZ, OSCAR	
	Examiner Sandra M. Nolan-Rayford	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 1-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment</u> |

DETAILED ACTION

Claims

1. Claims 1-25 are pending.

Pursuant to entry of the 12 October 2004 amendment ("the last response"), claims 16-25 were added.

There are no cancelled claims.

There are no withdrawn claims.

Claim Trees

2. The examiner is enclosing a sheet showing the claim trees for this case, the trees illustrate the dependency of the claims as they were recited in the last response.

Summary of Base Claims

3. The base claims of the case, i.e., claims 1 and 25, are summarized as follows:

Claim 1 covers a balloon "for use in a balloon catheter including a tubing", said balloon being burst resistant and comprising a nano-composite reinforced polymer matrix "consisting essentially of":

- a polymer, and
- a nano composite selected from carbon nano-tubes, a nano clay or nano-ceramic fibers,
- “a small amount” of lubricant to aid dispersion of the nanocomposite during blending of the matrix,

wherein the matrix has been formed by controlling:

- a. the volume or weight percent of nano composite in the matrix such that that percent is 0.20 to 20% by weight and the polymer is 80% to 99.80% of the matrix,
- b. the “wetting” of the nano composite in the matrix,
- c. the orientation of the nano composite in the matrix.

Claim 25 covers a balloon “for use in a balloon catheter including a tubing”, said balloon being burst resistant and comprising a nano-composite reinforced polymer matrix “including”:

- a polymer, and
- a nano composite selected from carbon nano-tubes, a nano clay or nano-ceramic fibers,

wherein the matrix has been formed by:

- i. dispersing the nano composite in the matrix with a small amount lubricant during melt compounding of the matrix,
- ii. subsequently extruding a tube, and
- iii. subsequently blow molding the balloon in the tube.

Notes:

I. Some of the dependent claims call for “balloon catheters”. In the absence of evidence to the contrary, the examiner will treat all of the claims as if the key features of the claims relate to the composition from which the balloons are made. The location of the other parts of a catheter are not germane to the patentability of these compositions.

II. The introduction of process limitations into the article claims of this case do not render these articles--whether balloons or balloon catheters--patentably distinct from similar articles made from similar compositions. It is presumed that the skilled artisan knows that s/he is “controlling” certain parameters via the selection of amounts and types of ingredients used in the claimed compositions. Also, in the absence of convincing objective evidence to the contrary, the process steps recited in applicant’s claims are deemed to be conventional in the art.

III. The structural features of catheters/balloons made from the compositions claimed in this application do not serve to distinguish the compositions from those suggested/taught by the prior art.

Comment re: Specification

4. The examiner notes that the specification contains no page numbers. It is suggested that the pages of the specification be numbered.

Rejections Withdrawn

5. The 35 USC 102 rejection of claims 1-15 as anticipated by Weber (US-2003/00655355), as recited in the 04 June 2004 office action ("the last office action"), is withdrawn in view of the Rule 131 declaration of inventor Oscar Jimenez, in which he declares that he conceived the idea of making the balloons covered by the claims of this application in the spring of 2001, before the 28 September 2001 provisional application filing date shown for the Weber publication.

6. The 35 USC 102 rejection of claims 1 and 12-15 as anticipated by Acquarulo et al (US 2003/0229184), as recited in the last office action, is withdrawn in order to apply one or more of the new rejections below.

New Objections/Rejections

Claim Objections

7. Claims 1-25 objected to because of the following informalities, which render the claims' scopes indefinite. Appropriate correction is required.

8. The informalities in the claims include:

- a. The phrase "a small amount" (claim 1, line 7 and claim 25, line 7) is indefinite.
- b. The use of "during blending" (claim 1, line 7) and "during melt compounding" (claim 25, lines 6-7) is indefinite because blending and melt compounding steps are not recited in those claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4, 8-9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the balloon catheter of claim 3" in line 1. There is insufficient antecedent basis for this limitation in claim 3, from which claim 4 depends.

Claim 8 recites the limitation "the balloon catheter of claim 7" in line 1. There is insufficient antecedent basis for this limitation in claim 7, from which claim 8 depends.

Claim 9 recites "the balloon of claim 8" in line 1. There is insufficient antecedent basis for this limitation in claim 8, from which claim 9 depends.

Claim 13 recited "the balloon catheter of claim 12" in line 1. There is insufficient antecedent basis for this limitation in claim 12, from which claim 13 depends.

Please correct the dependencies of these claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-3 and 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acquarulo (PCT publication WO 01/34685A1).

The PCT publication was supplied to the office with the last response. It is cited on the enclosed citation form. It corresponds to US 2003/0229184A1 because both the PCT publication and the US pre-grant publication claim the benefit of provisional application U.S. SN. 60/164,589, filed 10 November 1999.

The base claims are summarized above.

Acquarulo teaches, in the passage at page 5, line 28 through page 6, line 5, "intravascular shafts" having tubular shafts made from compositions containing nano clays and nylons. Its compositions contain 0.5 to 10% by weight (page 4, line 1) of a crosslinking promoter ("crosslinker"), such as triallyl(iso)cyanurate (page 4, lines 15-28) and 1-10% by weight (page 4, lines 12-14) of a nano clay that has a cationic surface treatment on it to render it less hydrophilic (page 4, lines 15-28). Both the clay surface treatment and the crosslinker are present when the clay and the polymer are melt mixed (page 4, lines 22 and 25).

Catheters are well-known "intravascular shafts".

Acquarulo fails to teach the use of carbon nanotubes (applicant's claims 4-5) or nano-ceramic fibers (applicant's claims 7-11) in its intravascular shafts.

The examiner notes that both the surface treatment and the crosslinker are organophilic, as is the polymer, because the surface treatment agent, the crosslinker and the polymer are organic [i.e., not hydrophilic] molecules and, therefore, they are interspersed, or dispersed together, easily. One of ordinary skill in the art would assume such compatibility when selecting the amounts and types of clays, crosslinkers and polymers to be used in the compositions of Acquarulo.

In the absence of convincing objective evidence to the contrary, the substitution of carbon nanotubes or nano-ceramic fibers in place of the nano clays of Acquarulo is deemed a matter of engineering choice, depending upon such factors as cost and the properties desired in the balloons/catheters produced.

Response to Arguments

14. Applicant's arguments filed in the last response have been fully considered but they are not persuasive. The arguments will be responded to in the order presented.

On pages 6-7 of the last response, applicants argue that the WO 01/34685 disclosure is distinct from the amended claims because the crosslinker and the radiation used in WO 01/34685 are excluded by the "consisting essentially of" phrase in claim 1.

However:

Only claims 1-24 include the phrase "consisting essentially of". As to them, applicant has the burden of showing that the use of additional ingredients/steps not included in the claims—here the crosslinker and/or radiation—would materially change

the character of the balloons/balloon catheters claimed here. Applicant has not met that burden. See MPEP 2111.03.

Claim 25 does not recite "consisting essentially of". Thus, the use of the crosslinker and/or radiation of the PCT publication fall within its scope. Claim 25 is obvious over the WO 01/34685 teachings.

Lastly, one would expect the organophilic crosslinking and surface treatment ingredients of the PCT publication to assist in the dispersion of fillers into the polymer matrix used there. See the 35 USC 103 rejection above.

Final Rejection

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee under 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

17. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication should be addressed to Sandra M. Nolan-Rayford, at telephone number 571/272-1495. She can be reached Monday through Thursday, from 6:30 am to 4:00 pm, ET.

If attempts to reach the examiner are unsuccessful, contact her supervisor, Harold Pyon, at 571/272-1498.

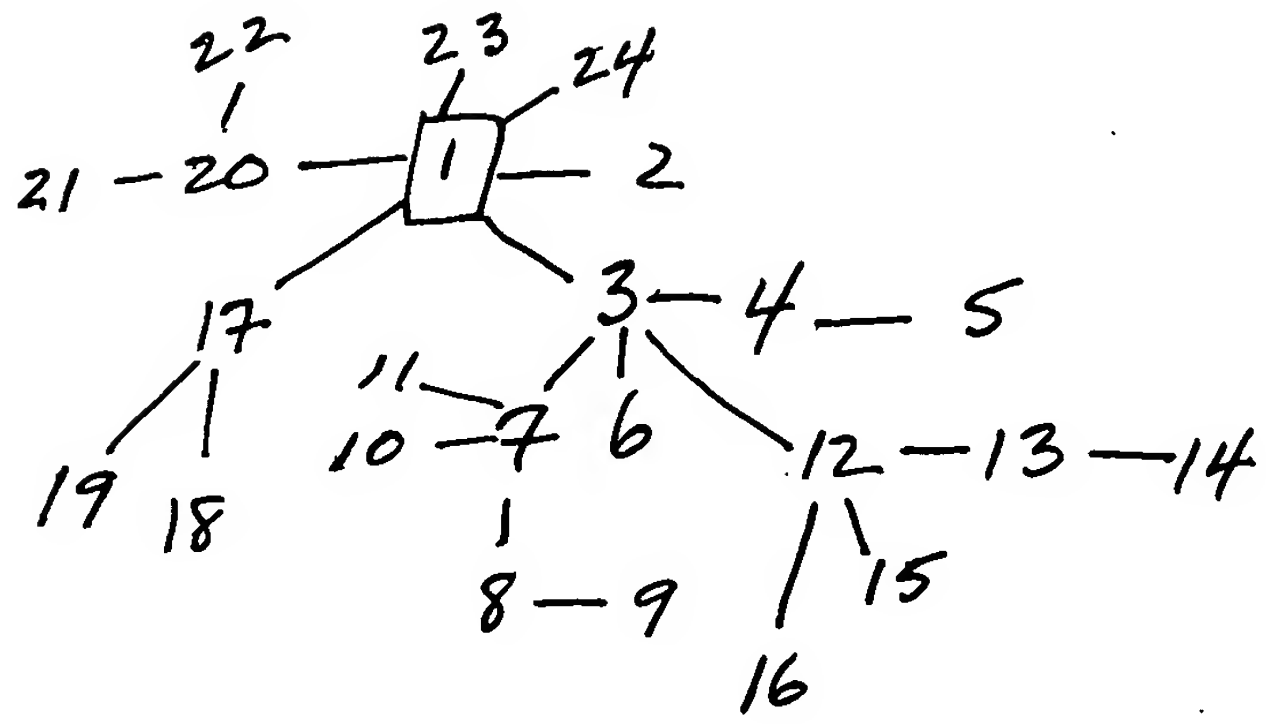
The fax number for patent application documents is 703/872-9306.

S. M. Nolan-Rayford
S. M. Nolan-Rayford
Primary Examiner
Technology Center 1700

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SN 10/046452
Claims as of 3/05

Claim Trees



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